111. (Amended) An energy delivery device for ablating biological tissue, comprising:

a flexible ablation assembly <u>having at least one ablation element encased therein and</u> defining an outer <u>emission</u> [ablation] surface from which ablation energy sufficient to ablate biological tissue is emitted,

C4

wherein the ablation assembly is adapted to be manipulated to one of a plurality of contact positions to generally conform the <u>emission</u> [ablation] surface to the biological tissue during tissue ablation.

C5

118. (New) The device of claim 111, wherein the at least one ablation element is flexible.

REMARKS

This is in response to the Office Action mailed on October 8, 2002 in regard to the above-identified patent application. Claims 81-83, 86, 87, 90 and 111 have been amended to more clearly describe Applicant's invention. Claim 118 has been added. Claims 81-111 and 118 are pending in the present case.

<u>35 USC §102 & 35 USC §103 REJECTIONS</u>

The Examiner has rejected Claims 81-110 under 35 USC §102(b) as being anticipated by McGee et al. ('695) and Claims 81-111 under 35 USC §102(e) as being anticipated by Cox et al. ('543). It is respectfully submitted that the Examiner should withdraw these rejections.

McGee et al. disclose an ablation device comprising an elongated shaft having several ablating elements attached to a distal end. More specifically, the ablating elements of McGee et al. are compressed onto the outer surface of the shaft (ring electrodes) or are applied to the outer

surface. See col. 6, lines 13-19. The device of McGee et al. requires contact with the tissue in order to create the desired ablation.

Cox et al. disclose a plurality of cryoprobes which enable the ablation of endocardial cardiac tissue around the pulmonary vein openings through a single purse string opening. The cryoprobes are designed such that the plurality of probe designs allow for the creation of the desired lesion set through a single purse string opening. The cryoprobes transmit thermal energy to the surface of the cardiac tissue at a point of contact between the cryoprobes and the tissue; tissue contact with the cryoprobes is necessary for transmission of thermal energy. See col. 3, lines 52-58 and col. 4, lines 40-46. As with McGee et al., the devices of Cox et al. require direct contact between the ablating element and the target tissue.

In contrast, the invention of Claim 81 specifically requires, in part, "a flexible ablation device having at least one ablation element *encased therein.*" (Emphasis added). The ablating element of the invention of Claim 81 does not require direct contact with the target tissue, as is required by the McGee et al. and Cox et al. devices. There is no teaching or suggestion in either McGee et al. or Cox et al. of a flexible ablation assembly having at least one ablation element *encased* therein. As stated above, the devices of both McGee et al. and Cox et al. require and depend on direct contact between the ablating element and a target tissue surface. Therefore, Applicants respectfully submit the rejection regarding Claim 81 has been overcome.

Furthermore, since Claims 82-110 depend from Claim 81, directly or indirectly, Applicants respectfully submit the rejections above regarding Claims 81-110 have been overcome.

Regarding Claim 111, Claim 111 has been amended in similar fashion to Claim 81 where the flexible ablation assembly includes "at least one ablation element encased therein." For the reasons set forth above with respect to Claim 81, Applicants respectfully submit the rejection regarding Claim 111 has been overcome. Additionally, since newly added Claim 118 depends from and further directly limits Claim 111, Applicants respectfully submit Claim 118 is in

form for allowance.

In view of the above amendments and the discussion relating thereto, it is respectfully submitted that the instant application, as amended, is in condition for allowance. Early reconsideration and reexamination is respectfully requested.

While Applicants believe no fee is due at this time, Applicants request that any fee due be deducted from deposit account 50-1894.

Respectfully Submitted,

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Appendix of Pending Claims

All currently pending claims are reproduced below for the Examiner's convenience.

81. An energy delivery device for ablating biological tissue, comprising:

a flexible ablation assembly, comprising:

a flexible ablation device having at least one ablation element encased therein; and

a means for directionally controlling ablation energy emitted therefrom.

82. The device of claim 81, wherein the at least one ablation element is adapted to emit ablation energy sufficient to ablate biological tissue.

83. The device of claim 82, wherein the flexible ablation assembly defines an outer emission surface from which ablation energy is emitted.

84. The device of claim 83, wherein the at least one ablation element is flexible.

86. The device of claim 83, wherein the ablation assembly further comprises an insulating element, the insulating element holding the ablation element in a fixed position relative to the emission surface.

87. The device of claim 86, wherein an exterior surface of the insulating element defines the outer emission surface.

88. The device of claim 87, wherein the insulating element is adapted to be substantially transparent to the ablation energy emitted therethrough by the at least one flexible ablation element.

89. The device of claim 88, wherein the means for directionally controlling the ablation energy is flexible.

90. The device of claim 87, wherein the means for directionally controlling the ablation energy is a shield device, whereby a portion of biological tissue adjacent to the emission surface is shielded from the ablation energy.

91. The device of claim 90, wherein the shield device is adapted to at least partially reflect ablation energy emitted by the at least one ablation element.

92. The device of claim 91, wherein the shield device is flexible.

93. The device of claim 92, wherein the at least one ablation element is an antenna adapted to emit electromagnetic energy.

94. The device of claim 93, wherein the at least one ablation element is adapted to emit electromagnetic energy in the microwave range.

95. The device of claim 94, wherein the electromagnetic energy is at about 434 MHz.

96. The device of claim 94, wherein the electromagnetic energy is at about 915 MHz.

97. The device of claim 94, wherein the electromagnetic energy is at about 2.45 GHz.

98. The device of claim 94, wherein the electromagnetic energy is at about 5.8 GHz.

99. The device of claim 94, wherein the antenna is a helical coil antenna.

100. The device of claim 94, wherein the antenna is a linear antenna.

101. The device of claim 90, wherein a longitudinal axis of the insulating element is generally coaxial with a longitudinal axis of the shield device.

102. The device of claim 81 further comprising a means for manual manipulation of the flexible ablation assembly.

103. The device of claim 102, wherein the manipulating means is a handle having proximal and distal ends, the flexible ablation assembly being operably attached to the distal end of the handle.

104. The device of claim 102, wherein the manipulating means is an elongated tubular member.

105. The device of claim 103 further comprising a shaft member operably disposed between the flexible ablation assembly and the handle.

106. The device of claim 105, wherein the shaft member is rigid.

107. The device of claim 106, wherein the shaft member is a metallic tube.

108. The device of claim 104, wherein the shaft member is malleable.

109. The device of claim 108, wherein the shaft member is a metallic tube.

110. The device of claim 108, wherein the shaft member is a coaxial cable.

111. An energy delivery device for ablating biological tissue, comprising:

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wherein the ablation assembly is adapted to be manipulated to one of a plurality of

contact positions to generally conform the emission surface to the biological tissue during tissue ablation.

118. The device of claim 111, wherein the at least one ablation element is flexible.